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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,630	08/18/2003	Martin J. Goldberg	3077.2	4457
22886	7590	01/10/2006	EXAMINER	
AFFYMETRIX, INC ATTN: CHIEF IP COUNSEL, LEGAL DEPT. 3380 CENTRAL EXPRESSWAY SANTA CLARA, CA 95051			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,630	GOLDBERG ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☒ Claim(s) 2 and 7 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/5/05</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Drawings

The drawings received on August 18, 2003 are acceptable.

Priority

The priority for the instant application is determined to be the filing date of the application - August 18, 2003. None of the parent application relied upon for priority conveys a method of manufacturing, wherein the method involves a "serial" processing. As this limitation is required in all of the independent claims of the present application, the priority to the parent application is denied.

Information Disclosure Statement

The references C1-C4, cited in the IDS received on July 5, 2005 are missing. These references have been lined-through in the enclosed PTO-1449.

Applicants are requested provide evidence that these references were received by the Office (post card receipt acknowledging the receipt of these references); or provide a supplemental IDS along with above-identified references.

Claim Objections

Claims 2 and 7 are objected to because of the following informalities:

Claim 2 recites the phrase, "wafers composed of more than one chips." It appears that the word, "chips" should read, "chip."

Claim 7 recites the phrase, "further processing a remainder of said of wafers." It appears that the second instance of the word, "of" (underlined) should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for reciting the word, “satisfactory,” because the term is a relative term which has no basis for determining its metes and bounds. For example, a certain criteria satisfactory to a person might not be satisfactory to another. The phrase reciting “predetermined criteria” or a phrase conveying similar meaning is suggested.

Claim 1 is indefinite for containing a period which demarcates the claim. Specifically, following the phrase, “isolating said sub-item from said sample of manufactured items,” a period is recited, rendering the claim confusing as to whether the steps following the punctuation is part of claim 1 or not. For the purpose of prosecution, it is assumed that the period is a typographical error.

Claims 2-6 are indefinite by way of their dependency on claim 1.

Claim 3 is indefinite for reciting the phrase, “wafers have from 400 to 6400 arrays,” but fails to recite what element is forming the “array,” rendering the metes and bounds of the claim indefinite.

Claim 5 is indefinite because it employs improper conjunction for identifying the elements of a Markush group. When elements are comprised in a Markush group, the conjunction “and” is employed so as to render definite the exact metes and bounds of the group from which elements are selected from. For example, the phrase reciting, “selected from the group consisting of A, B, C, and

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D,” conveys that the selected element must be from a single group made of A-D. However, the instant claim is analogous to the phrase reciting, “selected from the group consisting of A, B, C, or D,” which renders indefinite whether the group is A and B; A and C; A and D; B and C; A, B, and C; or A, B, and D; etc.

Claim 7 is indefinite for reciting the phrase, “isolating one or more of said nucleic acid arrays from said wafers,” because the step previous recites that at least one of the wafers are selected. Therefore, it becomes confusing whether the isolation of one ore more of the nucleic acid arrays is from the selected wafers or the non-selected wafers. For the purpose of prosecution, the former interpretation is assumed.

Claims 8-13 are indefinite by way of their dependency on claim 7.

Claim 11 is indefinite for reciting the phrase, “wafers are made by inkjet synthesis.” It is unclear how a wafer can be made from an inkjet. It appears that Applicants mean to state that the nucleic acid arrays are formed on the wafer by inkjet synthesis. This interpretation is assumed for prosecution.

Claims 12 and 13 recite the limitation, “said chip” or “said plurality of chips.” There is insufficient antecedent basis for these limitations.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described

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in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

While claims are their own description (“original claims constitute their own description” according to *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); and according to *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976)), the instant claims embrace the scope of which pertains to non-analogous art, to which the instant specification fails to describe.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., > *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); < *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.

However, these early opinions did not address the quality or specificity of particularity that was required in the description, i.e., how much description is enough (see MPEP 2163 (I)). In addition, MPEP 2163(I)(A) clearly states that “the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was “ready for patenting” such as by the disclosure of drawings or structural chemical formulas that show that

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the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.

Instant claim 1 is reproduced below:

1. A method of manufacturing a plurality of items, said items comprising more than one sub-item, in serial, said method comprising:

manufacturing a plurality of items each item comprising more than one sub-item in serial over a period of time;

selecting a sample of manufactured items from the serial production process;

isolating said sub-item from said sample of manufactured items [[.]]¹;

identifying the quality of the selected sub-item; and

if said quality is determined to be satisfactory, then subjecting a remainder of said manufactured items produced in serial to further processing.

As recited, the claimed method embraces a method of quality control of items which can be drawn to mechanical parts, or semiconductor synthesis.

Clearly the instant specification is drawn to only to a method of quality controlling biological arrays (nucleic acid, peptides, for example; *see* instant claim 5) which are synthesized on a substrate (or wafer).

All of the description provided by the instant specification points to a method which pertains to arrays of biological materials produced on a substrate(s), and does not contain any description pertaining to methods “generically” drawn to “items” comprising “more than one sub-item” as a mechanical part (item) is made of sub-items; or a semiconductor chip (item) is made of

¹ See assumption made in the rejection under 35 U.S.C. 112, second paragraph.

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electrical wiring (sub-items), so as to provide an adequate written description for the claimed breadth.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Welling et al.

(U.S. Patent No. 5,420,796, issued May 30, 1995).

Welling et al. disclose a method of manufacturing a plurality of integrated circuit (herein, IC), said method comprising the steps:

a) manufacturing a plurality of wafers (items) comprising more than one sub-items (or IC; *see* column 3, lines 18-20 in the phrase, “[a] typical wafer has room enough for many IC devices”);

b) selecting and isolating a sub-item and identifying the quality (*see* column 3, lines 26-28 in the phrase, “inspection is performed by employing an atomic force microscope (AFM) to scan a predetermined region of the wafer”);

c) based on the determined quality, subjecting the remainder of the wafer for further processing (*see* column 3, lines 56-59) or discarding the wafer via use of a computer, thereby anticipating claims 1 and 2.

With regard to claims 3 and 6, it is well known that the wafer comprising the plurality of ICs are cut into separate devices upon completion of fabrication (see column 2, lines 27-29 which recites that “several thousand or more ICs are sampled out” from a wafer).

Therefore, the invention as claimed is anticipated by Welling et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer.

A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,309,831 B1 (herein, the ‘831 patent) in view of Chen et al. (U.S. Patent No. 5,966,459, issued October 12, 1999, filed July 17, 1997; IDS ref# A6; herein, the ‘459 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Preliminarily, it should be noted that while the instant application is a continuation-in-part of 10/044,428 which is a continuation of 09/245,329 (the ‘831 patent), and there was at least one restriction made therein. None of the restriction requirements restricted the claims of the instant application and the patented claims of the ‘329. Hence, there is no statutory bar under 35 U.S.C. 121 for making the instant obviousness-type double patenting rejection.

Claim 1 of the ‘831 patent is drawn to a method of manufacturing a plurality of items in parallel comprising:

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- a) selecting a sample (or sub-item) of items from a plurality of items undergoing a manufacturing process;
- b) subjecting said sample (or sub-item) to further manufacturing processing;
- c) identifying a quality of the selected sample (or sub-item); and
- d) if said quality is determined to be satisfactory, then subjecting the remainder of said items to said further processing.

Instant claim 1 is drawn to a method of manufacturing a plurality of items, said items comprising more than one sub-item, said method comprising:

- a) manufacturing a plurality of items each item comprising more than one sub-item in serial over a period of time;
- b) selecting a sample of manufactured items from the serial production process;
- c) isolating said sub-item from said sample of manufactured items;
- d) identifying a quality of said selected sub-item; and
- e) if said quality is determined to be satisfactory, then subjecting a remainder of said manufactured items produced in serial to further processing.

The difference between claim 1 of the '831 patent versus that of the instant application is in that the method in the '831 patent is performed "parallel" while the method exemplified by instant claim 1 is performed "serial."

However, whether the production of the samples are made via serial process or parallel process, the method pertains to selecting the manufactured items for defects regardless of whether the items were made via parallel or serial process. In other words, the method is drawn to performing the steps after the items have been manufactured. Hence, whether parallel or serial

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means of production has no bearing on how the quality of the items are accessed, coupled with the fact that methods of parallel or serial processing is well known in the industry of device fabrication.

Hence, instant claim 1 fails to patentably distinguish itself over claim 1 of the '831 patent, rendering the claim obvious over claim 1 of the '831 patent.

With regard to instant claim 2, the plurality of items is disclosed as being chips on a wafer.

With regard to instant claim 3, the artisans disclose that a typical wafer may be populated with numerous probe arrays (*see* column 6, lines 29-30), wherein the probe arrays are disclosed as being synthesized via VSLIPTM (very large scale immobilized polymer synthesis; *see* column 7, lines 10-12). Absent evidence to the contrary, the method of the '831 patent would necessarily produce wafers having from 400 to 6400 arrays. In addition, column 9, lines 46-47) of the '831 patent explicitly discloses that a single wafer could comprise 4 to 400 biological chips.

With regard to instant claim 4, claim 3 of the '831 patent recites that the chips include biological material.

With regard to instant claim 5, claim 4 of the '831 patent recites that the biological material is selected from the group consisting of DNA, RNA, amino acids, and analogs thereof.

With regard to instant claim 6, claim 21 of the '831 patent recites that the array is separated from the substrate (or wafer), wherein the separation is disclosed as being scribing (column 7, lines 23-24) via use of a cutter (column 7, line 39), followed by its breaks at the scribed position (column 7, lines 43-52).

With regard to instant claim 7, the claim is further obvious in view of the fact that the claimed method is not limited to producing a single wafer. As understood in the art, particularly in the microarray synthesis, a plurality of a particular array-type is mass produced. Hence, the practice of mass producing a particular array-type would necessarily involve fabrication of wafers which are

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duplicates (as they are drawn to the particular array-type). One of ordinary skill in the art would have been motivated to apply the method claims of the '831 patent to quality control not only a single wafer but a plurality of duplicate wafers, so as to ensure that mass produced arrays meet the desired quality. In addition, the '459 patent evidences a common knowledge in the art of substrate fabrication, wherein the patent discloses:

“As is known in the semiconductor manufacturing art, a production lot of wafers can ben any selected number of wafers. As is also known in the semiconductor manufacturing art, it is not practical to scan each [wafer] for defects. Therefore, one wafer is selected from each production lot.” (column 4, lines 8-15)

Hence, one of ordinary skill in the art would have been motivated to select a particular wafer or wafers of the lot for quality control method provided for by the '831 patent.

With regard to instant claim 8, claim 7 of the '831 patent recites that the arrays are manufactured by light directed synthesis.

With regard to instant claim 9, claim 8 of the '831 patent recites that the arrays are manufactured by nucleic acid spotting.

With regard to instant claim 11, claim 9 of the '831 patent recites that the arrays are manufactured by ink jet synthesis.

With regard to instant claim 10, Figure 4 of the '831 patent clearly contemplates that packaging involves putting the arrays in to cartridges (element 207 of Figure 4).

With regard to instant claim 12, claim 16 of the '831 patent recites that a second test is performed on a chip of the substrate (or wafer) and if the chip fails the second test, the substrate is discarded.

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With regard to instant claim 13, claim 17 of the '831 patent recites that a third test is performed on a chip of the substrate (or wafer) and if the chip fails the test, the substrate is discarded.

Therefore, instant claims 1-13 are obvious over claims 1-24 of the '831 patent in view of the '459 patent.

Conclusion

No claims are allowed.

Inquiries

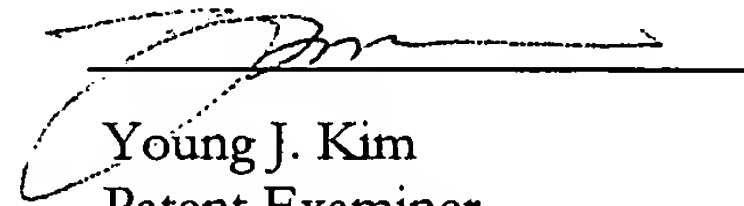
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be

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sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
1/6/2006

**YOUNG J. KIM
PATENT EXAMINER**

yjk